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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,728	01/22/2001	Habib Zaghouni	ALLIA.143C1	6688

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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/25/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,728

Applicant(s)

Zaghouni

Examiner

Patrick J. Nolan

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above, claim(s) 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 6) ☒ Other: Sequence Letter

Part III DETAILED ACTION

1. Claims 1-20 and newly added claims 21-28 are pending.
2. Applicant's election of Group I, claims 1-7 and newly added claims 21-28 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
Accordingly, claims 8-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.
3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 and 21-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no support for the phrase "is derived from a protein responsible for an autoimmune disease" as recited in amended base claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office

action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

6. Claims 1-7 and 21-28 are rejected under 35 U.S.C. § 103 as being unpatentable over Bona et al. (26) in view of Liu et al., (59) and Karpus et al., (51).

Bona et al., teaches a fusion protein comprising an IgG immunoglobulin with its CDR3 region replaced by a viral peptide, wherein said fusion protein is endocytosed by cells bearing an Fc receptor, processed by said cells and wherein said cell express said viral peptides, wherein said viral peptides are T cell peptides which specifically stimulate T cells (abstract, in particular).

The claimed invention differs from the prior art teachings by the recitations of using T cell receptor peptide agonists derived from proteolipid or myelin basic protein. However, Liu et al., teaches the induction of tolerance in EAE mice with the use of a peptide derived from MBP (abstract, in particular). Liu et al., also teaches that induction of tolerance with self-peptide takes time to develop (see abstract, in particular). Karpus et al., teaches the induction of tolerance in EAE mice with the use of a peptide from proteolipid, (see abstract, in particular). In addition Bona et al., teaches that using Immunoglobulins (IG's) replaced in the CDR3 region are useful in targeting antigens to antigen presenting cells because IG's have longer half lives than synthetic peptides, (page 23 in particular). Bona et al., also teaches that the method of delivering antigens to cells via IG's "can be extended to express other biologically important epitopes such as tumor antigens, oncogenes or self antigens which can be used in the antitumor therapy or the therapy of autoimmune diseases" (page 29, in particular).

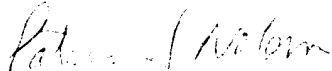
One of ordinary skill in the art at the time the invention was made would have been motivated to substitute viral peptide-IgG fusion proteins taught by Bona et al., for a T cell receptor agonist derived from proteolipid taught by Karpus et al., or from myelin basic protein, as taught by Liu et al., because peptide-IgG fusion proteins are better for delivery of antigens of interest

because IG's have longer half lives than synthetic peptides as taught by Bona et al., and longer half life is necessary for tolerance induction to occur as taught by Liu et al., and because Karpus et al., and Liu et al., teach the successful use of a peptide agonist, for treating EAE, wherein said peptide is derived from proteolipid protein or myelin basic protein. In addition, it would have also been obvious to one of skill in the art to use both self-protein agonists, PLP and MBP, in a single fusion protein since both MBP and PLP are well known autoantigens for the same autoimmune disease EAE. Inducing tolerance in an animal to both known autoantigens for a specific autoimmune disease would have been obvious to one of skill in the art. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

7. It is noted the IDS submitted on 12 March 2001 was not considered because it is a duplicate of the IDS submitted on 2-11-02.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

9. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.


Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
June 24, 2002